


PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

(Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference 44735	FOR FURTHER ACTION		See Form PCT/PEA/416
International application No. PCT/IL2008/001292	International filing date (day/month/year) 24.09.2008	Priority date (day/month/year) 01.10.2007	
International Patent Classification (IPC) or national classification and IPC INV. A61F2/00			
Applicant Contipi Ltd.			
<p>1. This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.</p> <p>2. This REPORT consists of a total of <u>6</u> sheets, including this cover sheet.</p> <p>3. This report is also accompanied by ANNEXES, comprising:</p> <p style="margin-left: 20px;">a. <input checked="" type="checkbox"/> sent to the applicant and to the International Bureau a total of <u>6</u> sheets, as follows:</p> <p style="margin-left: 40px;"><input checked="" type="checkbox"/> sheets of the description, claims and/or drawings which have been amended and are the basis of this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions).</p> <p style="margin-left: 40px;"><input type="checkbox"/> sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box.</p> <p style="margin-left: 20px;">b. <input type="checkbox"/> (sent to the International Bureau only) a total of (indicate type and number of electronic carrier(s)) , containing a sequence listing and/or tables related thereto, in electronic form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).</p>			
<p>4. This report contains indications relating to the following items:</p> <p><input checked="" type="checkbox"/> Box No. I Basis of the report</p> <p><input type="checkbox"/> Box No. II Priority</p> <p><input checked="" type="checkbox"/> Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability</p> <p><input type="checkbox"/> Box No. IV Lack of unity of invention</p> <p><input checked="" type="checkbox"/> Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement</p> <p><input checked="" type="checkbox"/> Box No. VI Certain documents cited</p> <p><input type="checkbox"/> Box No. VII Certain defects in the international application</p> <p><input type="checkbox"/> Box No. VIII Certain observations on the international application</p>			
Date of submission of the demand 2009-07-29		Date of completion of this report 08.12.2009	
Name and mailing address of the international preliminary examining authority:  European Patent Office D-80298 Munich Tel. +49 89 2399 - 0 Fax: +49 89 2399 - 4465		Authorized officer Serra i Verdaguer, J Telephone No. +49 89 2399-8198	



**INTERNATIONAL PRELIMINARY REPORT
ON PATENTABILITY**

International application No.
PCT/IL2008/001292

Box No. I Basis of the report

1. With regard to the **language**, this report is based on
- ☒ the international application in the language in which it was filed
 - ☐ a translation of the international application into , which is the language of a translation furnished for the purposes of:
 - ☐ international search (under Rules 12.3(a) and 23.1(b))
 - ☐ publication of the international application (under Rule 12.4(a))
 - ☐ international preliminary examination (under Rules 55.2(a) and/or 55.3(a))
2. With regard to the **elements*** of the international application, this report is based on *(replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report):*

Description, Pages

1-33 as originally filed

Claims, Numbers

1-46 filed with telefax on 29.07.2009

Drawings, Sheets

1/20-20/20 as originally filed

- ☐ a sequence listing and/or any related table(s) - see Supplemental Box Relating to Sequence Listing
3. ☐ The amendments have resulted in the cancellation of:
- ☐ the description, pages
 - ☐ the claims, Nos.
 - ☐ the drawings, sheets/figs
 - ☐ the sequence listing (*specify*):
 - ☐ any table(s) related to sequence listing (*specify*):
4. ☐ This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).
- ☐ the description, pages
 - ☐ the claims, Nos.
 - ☐ the drawings, sheets/figs
 - ☐ the sequence listing (*specify*):
 - ☐ any table(s) related to sequence listing (*specify*):
5. ☐ This opinion has been established taking into account the **rectification of an obvious mistake** authorized by or notified to this Authority under Rule 91 (Rule 70.2 (e)).
6. ☐ Supplementary international search report(s) from Authority(ies) have been received and taken into account in drawing up this report (Rule 45bis.8(b) and (c)).

**INTERNATIONAL PRELIMINARY REPORT
ON PATENTABILITY**

International application No.
PCT/IL2008/001292

Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

1. The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non-obvious), or to be industrially applicable have not been examined in respect of:

☐ the entire international application,

☒ claims Nos. 35-46

because:

☒ the said international application, or the said claims Nos. 35-41 relate to the following subject matter which does not require an international preliminary examination (*specify*):

see separate sheet

☐ the description, claims or drawings (*indicate particular elements below*) or said claims Nos. are so unclear that no meaningful opinion could be formed (*specify*):

☐ the claims, or said claims Nos. are so inadequately supported by the description that no meaningful opinion could be formed (*specify*).

☒ no international search report has been established for the said claims Nos. 35-46

☐ a meaningful opinion could not be formed without the sequence listing; the applicant did not, within the prescribed time limit:

☐ furnish a sequence listing on paper complying with the standard provided for in Annex C of the Administrative Instructions, and such listing was not available to the International Preliminary Examining Authority in a form and manner acceptable to it.

☐ furnish a sequence listing in electronic form complying with the standard provided for in Annex C of the Administrative Instructions, and such listing was not available to the International Preliminary Examining Authority in a form and manner acceptable to it.

☐ pay the required late furnishing fee for the furnishing of a sequence listing in response to an invitation under Rules 13ter.1(a) or (b) and 13ter.2.

☐ a meaningful opinion could not be formed without the tables related to the sequence listings; the applicant did not, within the prescribed time limit, furnish such tables in electronic form complying with the technical requirements provided for in Annex C-bis of the Administrative Instructions, and such tables were not available to the International Preliminary Examining Authority in a form and manner acceptable to it.

☐ the tables related to the nucleotide and/or amino acid sequence listing, if in electronic form only, do not comply with the technical requirements provided for in Annex C-bis of the Administrative Instructions.

☐ See separate sheet for further details

**INTERNATIONAL PRELIMINARY REPORT
ON PATENTABILITY**

International application No.
PCT/IL2008/001292

Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes: Claims	<u>12,13,17,19,29-34</u>
	No: Claims	<u>1-11,14-16,18,20-28</u>
Inventive step (IS)	Yes: Claims	
	No: Claims	<u>12,13,17,19,29-34</u>
Industrial applicability (IA)	Yes: Claims	<u>1-34</u>
	No: Claims	

2. Citations and explanations (Rule 70.7):

see separate sheet

Box No. VI Certain documents cited

1. Certain published documents (Rule 70.10)

and / or

2. Non-written disclosures (Rule 70.9)

see separate sheet

Re Item III

Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

The subject-matter of claim 35 to 41, discloses a method of ameliorating urinary incontinence. The method comprises the step of intra-vaginally inserting the apparatus. The International preliminary searching authority is not required to establish an opinion with regard to novelty, inventive step and industrial applicability on methods for treatment of the human body by surgery or therapy (Rule 39.1(iv)).

Re Item V

Reasoned statement with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Reference is made to the following documents:

D1: WO 2008/010214 A (CONTIPI LTD [IL]; ZIV ELAN [IL]; GILAN JACOB [IL]; SINAI NIR [IL]; BAU) 24 January 2008 (2008-01-24)
D2: WO 2006/097935 A (CONTIPI LTD [IL]; SINAI NIR [IL]; ZIV ELAN [IL]; BUDER IDAN [IL]; GILA) 21 September 2006 (2006-09-21)
D3: WO 2005/087154 A (CONTIPI LTD [IL]; ZIV ELAN [IL]) 22 September 2005 (2005-09-22)

2. The present application does not meet the criteria of Article 33(1) PCT, because the subject-matter of claim 1 is not new in the sense of Article 33(2) PCT.

The document D3 discloses (page 19 and figures 13 c and d): an apparatus for treating urinary incontinence, comprising: a support section (1390) adapted for providing at least one of urethral support and pressure against a portion of the urethra; an anchoring section (1386) adapted for resisting movement of said apparatus; a normally open expansion mechanism adapted to urge said support section radially outwards; and a conversion mechanism adapted to provide a mechanical gain such that an axial force used to activate the conversion mechanism is substantially smaller than the reduction in radial force exerted by said support section.

It should be noted that the features "expansion mechanism" and "conversion

**INTERNATIONAL PRELIMINARY
REPORT ON PATENTABILITY
(SEPARATE SHEET)**

International application No.

PCT/IL2008/001292

mechanism" are very broad. Therefore, the examiner is of the opinion that the cross bars connected to the pull string shown in figures 13c and 13d can be considered the expansion mechanism and the string 1398 in combination with the cross bars, the conversion mechanism. For example the embodiments shown in figures 5 and 6 of the present application are similar to those of figures 13c and 13d of D3

3. Dependent claims 2 to 34 do not contain any features which, in combination with the features of any claim to which they refer, meet the requirements of the PCT in respect of novelty or inventive step, see documents D2 and D3 and the corresponding passages cited in the search report.

Re Item VI

Certain documents cited

Certain published documents (Rule 70.10)

Application No Patent No	Publication date (day/month/year)	Filing date (day/month/year)	Priority date (valid claim) (day/month/year)
WO-A-2008/010214	24.01.2008	16.07.2007	16.07.2006

Although Document D1 does constitute prior art within the meaning of Rule 64.1(b) PCT it appears to disclose all the features of the claims.

No check has been made as to whether the priority of this prior application has been validly claimed.

CLAIMS

1. An apparatus for treating urinary incontinence, comprising:
 - (a) a support section adapted for providing at least one of urethral support and pressure against a portion of the urethra;
 - (b) an anchoring section adapted for resisting movement of said apparatus;
 - (c) a normally open expansion mechanism adapted to urge said support section radially outwards; and
 - (d) a conversion mechanism adapted to provide a mechanical gain such that an axial force used to activate the conversion mechanism is substantially smaller than the reduction in radial force exerted by said support section.
2. Apparatus according to claim 1, wherein said support section comprises a plurality of support arms.
3. Apparatus according to claim 2, wherein said support section is configured to provide urethra support.
4. An apparatus according to claim 3, wherein the expansion mechanism is adapted to urge without a force applied from outside the apparatus.
5. An apparatus according to claim 3 or claim 4, wherein the conversion mechanism is adapted to respond to a deforming force by axially extending, thereby causing radial collapse of the support arms.
6. An apparatus according to claim 5, wherein the expansion mechanism is adapted to revert to the normally open state upon removal of the force.
7. An apparatus according to any of claims 3-6, wherein said distal ends of said support arms apply sufficient force to vaginal walls to ameliorate incontinence.

8. An apparatus according to any of claims 3-7, wherein said conversion mechanism is adapted to urge said support arms radially inwards in response to a force applied from outside the apparatus.
9. An apparatus according to claim 8, wherein the conversion mechanism comprises a string attached to a hub of the expansion mechanism.
10. An apparatus according to any of claims 3-9, comprising:
a loading element connected to the expansion mechanism and adapted to urge at least a portion of the expansion mechanism axially towards said anchoring section.
11. An apparatus according to claim 10, wherein the loading element comprises an elastic string adapted for attachment to a hub section of the expansion mechanism.
12. Apparatus according to any of claims 3-11, wherein said support arms are hinged.
13. Apparatus according to claim 12, wherein said support arms each comprise at least two hinges.
14. Apparatus according to any of claims 3-13, wherein said support arms are flexible.
15. Apparatus according to any of claims 3-14, wherein urethral support is mid-urethral support.
16. Apparatus according to any of claims 3-15, wherein said expansion mechanism and said support section are integrally attached to one another.

17. Apparatus according to claim 16, wherein said integral attachment to one another comprises integral hinges.
18. Apparatus according to any of claims 3-15, wherein said expansion mechanism and said support section comprise separate elements assembled to form the apparatus.
19. Apparatus according to claim 18, wherein said expansion mechanism and said support section are connected by hinges.
20. An apparatus according to any of claims 3-19, wherein said apparatus is flexible.
21. Apparatus according to any of claims 3-20, wherein the expansion mechanism comprises elastic portions.
22. Apparatus according to any of claims 3-21, wherein the expansion mechanism comprises rigid portions.
23. Apparatus according to any of claims 1-22, wherein urethral support includes bladder neck support.
24. Apparatus according to any of claims 1-23, comprising a cover.
25. Apparatus according to claim 24, comprising a cover collapse mechanism.
26. Apparatus according to any of claims 1-25, wherein said apparatus is rotationally symmetric.
27. Apparatus according to any of claims 1-26, wherein said apparatus is configured to operate independently of a rotational insertion angle.

28. Apparatus according to any of claims 1-27, wherein said apparatus is configured to allow passage of vaginal discharges therethrough when inserted.
29. An apparatus according to any of claims 1-28, wherein the expansion mechanism and the conversion mechanism are separate elements.
30. An apparatus according to any of claims 1-29, wherein substantially smaller is less than 70% of the reduction in radial force exerted by the support section.
31. An apparatus according to any of claims 1-29, wherein substantially smaller is less than 50% of the reduction in radial force exerted by the support section.
32. An apparatus according to any of claims 1-29, wherein substantially smaller is less than 40% of the reduction in radial force exerted by the support section.
33. An apparatus according to any of claims 1-29, wherein substantially smaller is less than 30% of the reduction in radial force exerted by the support section.
34. An apparatus according to any of claims 1-29, wherein substantially smaller is less than 20% of the reduction in radial force exerted by the support section.
35. A method for ameliorating urinary incontinence, the method comprising:
- (a) intra-vaginally inserting an apparatus which provides at least one of support of pressure to a urethra, by a support section thereof;
 - (b) collapsing said support section after said insertion by application of force generally along an axis of said vagina;
 - (c) repositioning said apparatus by said axial force; and
 - (d) reducing said force to allow said support section to uncollapse and re-function as a support section.

36. A method according to claim 35, wherein said collapsing comprises displacing a radially outwards urging element by said force.
37. A method according to claim 35, wherein said collapsing comprises displacing a rigidizing element by said force.
38. A method according to any of claims 35-37, wherein said collapsing comprises applying a greater axial force to start collapsing than to complete collapsing.
39. A method according to any of claims 35-38, wherein said collapsing comprises first increasing a radial extent of said support section as part of said collapsing.
40. A method according to any of claims 35-39, comprising removing said apparatus using said force after (c).
41. A method according to any of claims 35-40, wherein inserting comprises inserting in a manner substantially oblivious to a rotational orientation of said apparatus.
42. An apparatus for treating urinary incontinence, comprising:
(a) an anchor section comprising a plurality of anchor legs; and
(b) a support section axially aligned with the anchor section and comprising a plurality of support arms;
wherein no anchor leg is in direct axial alignment with a support arm.
43. Apparatus according to claim 42, wherein a number of anchor legs is equivalent to a number of support arms.
44. An apparatus for treating urinary incontinence, comprising:
(a) an anchor section comprising a plurality of anchor legs and an anchor connector; and

(b) a support section comprising a plurality of support arms and a support connector;

wherein the anchor connector and support connector are adapted for connection one to another.

45. An apparatus according to claim 44, wherein connection of the anchor connector and support connector one to another fixes an axial alignment of the anchor legs and support arms.

46. An apparatus according to claim 44, wherein connection of the anchor connector and support connector one establishes a rotating joint between the anchor section and the support section.